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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,254

08/01/2003

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07/07/2009

Rutan & Tucker, LLP.

611 ANTON BLVD

SUITE 1400

COSTA MESA, CA 92626

EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

07/07/2009

PAPER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/633,254
Filing Date: August 01, 2003
Appellant(s): EVANS ET AL.

Todd W. Wight
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 20, 2009 appealing from the Office action mailed June 18, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,509,516	RICHMOND	04-1985
4,799,484	SMITH et al.	01-1989
6,612,977	STASKIN et al.	09-2003

6,755,781

GELLMAN

06-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 120-123, 125-128, 131, and 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (6,612,977) in view of Richmond (4,509,516). With respect to claims 1-4, 120-123, 125-128, and 131, Staskin et al. disclose the invention substantially as claimed. Staskin et al. disclose, at least in figures 1, 1A, 4, 12A, 12B, 16A-16D, and 18A-18E; a system including an introducer needle (60A or 60B) having a first end (170) and a second end (170), each having a flattened portion (e.g., 126); a handle (64G) having a latch mechanism (198), an implant member (42) having an end and a connector (56B—see fig. 12B) joining an end of the implant member to the second end (58) of the introducer needle; where the connector includes a central portion (a hinge between 112' and 54B), a first arm (54B) pivotally connected to the central portion and having a first opening (116), and a second arm (112') pivotally mounted to the central portion and having a first projection (114); where the needle is curved (see fig. 16A) and symmetrical (about the longitudinal axis), where the flattened portion or tip (at 174) of the first end (of needle 60B) differs in size and shape or configuration from the flattened end of the second portion (170) or second flattened portion, and where the needle has a flared section (tapered portion of 170 as seen on the left side of fig. 16A) having a cross-sectional profile that is at least as large as the cross-sectional profile of the connector, where the needle has rounded tip, an arcuate shape, and a circular cross-section; where the needle has an assymetric shape (with respect to an axis in the middle of the needle and transverse to the longitudinal axis of the needle), where the implant member has a central portion (66 or 42 with

respect to claim 131) having first and second ends and first and second arms connected respectively to the first and second ends, and where the first and second arms (48 and 50 with respect to claim 131 or end portions of 42 with respect to claims 126-128) have a plurality of openings arranged in a two-dimensional pattern (i.e., the mesh of 42 has a pattern). However, Staskin et al. do not disclose that the flattened portion of each end of the needle has an opening therethrough. Richmond teaches, at least in col. 2, lines 67 to col. 3, line 4 and col. 4, lines 41-44 and 51-60; an introducer needle with an opening (18) at each end of the needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Richmond, to include an opening in each end of the needle of Staskin et al. Such a modification would allow the needle of Staskin et al. to receive an implant (absent a connector) or a suture and thread the implant or suture through a narrow opening between organs or tissues.

With respect to claim 132, Staskin et al. also disclose the invention substantially as claimed. Staskin et al. disclose, at least in figures 1, 1A, 4, 12A, 12B, 16A-16D, and 18A-18E; a system including an introducer needle (60A or 60B) having an elongated shaft connecting first and second spatulated sections (e.g., 126), where at least one of the spatulated sections has a tip, a constant width portion, where the shaft has straight portion connected to a curved portion, the first flat spatulated section connected to the curved portion and a flared section (tapered portion of 170) having a cross-sectional profile that covers a cross-section profile of the first flat spatulated section; and a handle (64G) having housing with an elongated portion with a distal end opening, and an elastically biased latch portion (198) having a projection. However, Staskin et al. do not disclose that the constant width portion has an opening therethrough. Richmond teaches, at least in col. 2, lines 67 to col. 3, line 4 and col. 4, lines 41-44 and 51-60; an introducer

needle with an opening (18) at each end of the needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Richmond, to include an opening in each end of the needle of Staskin et al. Such a modification would allow the needle of Staskin et al. to receive an implant (absent a connector) or a suture and thread the implant or suture through a narrow opening between organs or tissues.

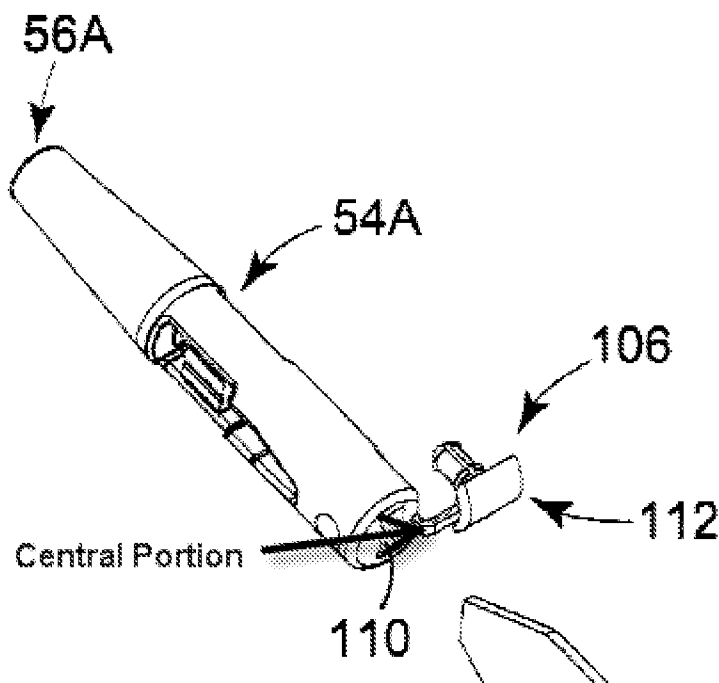
Claim 124 is rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (6,612,977) in view of Richmond (4,509,516), and further in view of Smith et al (4,799,484). Staskin et al. in view of Richmond disclose the invention substantially as claimed, but do not disclose that a portion of the needle has an oval cross section. Smith et al. teach, in figures 5a and 5b and in col. 2, lines 19-26 and col. 3, line 58 to col. 4, line 14; a needle with a circular or an oval cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Smith et al., to modify at least a portion of the needle of Staskin et al. in view of Richmond, so that it has an oval cross section. Such a configuration would ease the needle's penetration and rotation in tissue or material where the needle is applied.

Claims 129 and 130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (6,612,977) in view of Richmond (4,509,516), and further in view of Gellman (6,755,781). Staskin et al. in view of Richmond disclose the invention substantially as claimed, but do not disclose, inter alia, an implant member with an elongated body and a support portion with a plurality of slits as claimed. Gellman teaches, at least in figures 1-3, 6A, and 6B, a flexible, bioabsorbable implant member with an elongated body and a support portion with a plurality of slits (10) as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Gellman, to configure the implant member so

that it is formed with a flexible material and a plurality of slits as claimed. Such an implant member would be strong and bioabsorbable, while the slits would allow tissue ingrowth into the implant member, where ingrown tissue would provide further buttressing for the implant member and the organs or tissues being supported by the implant member.

(10) Response to Argument

The allegation on page 5, paragraph VII(A)1(a) of the brief, that Staskin fails to disclose a first arm pivotally mounted to the central portion, is incorrect. That is, the central portion is a flexible hinge between 112' and 54b that allows relative pivotal motion between 112' and the central portion. Also, element 112' can also be "fixed," while the central portion pivots relative to the first arm. For an illustration of the central portion, i.e., a hinge, the Appellant is directed to the excerpt from figure 12A of Staskin below, which shows a central portion between elements 112 and 54A, which are respectively analogous to elements 112' and 54b.



Moreover, second arm 112' (analogous to element 112 in the figure above) is also pivotally mounted to the central portion. In short, since the central portion is a flexible hinge, both arms (54A or 54B and 112 or 112') are capable of pivotal movement relative to the central portion. That is, the central portion, which is made of a flexible polymeric material (according to Staskin, col. 17, lines 57-61), is hingedly connected to both arms.

The allegation on page 8, paragraph VII(A)1(b) of the brief, that Richmond fails to supply features from Staskin, is incorrect. Richmond was not applied by the Examiner to show or describe a connector joining the end of an implant member to a flattened portion of a second end of an introducer needle. Richmond was solely applied, in the rejection, for the teaching regarding an introducer needle possessing openings at its ends--a teaching applied for curing Staskin's deficiencies regarding such openings.

The allegation on page 9, paragraph VII(A)2 of the brief, that the Staskin connector (56B) will always have a cross-sectional profile greater than the needle, is incorrect. As pointed out by the Examiner, element 170 of the needle of Staskin, as seen at the left side of fig. 16A, includes a flared portion adjacent to element 60A (not the flared portion distal of element 130), which has a cross-section at least as large as a cross-sectional profile of the connector (at its narrow end).

The allegation on page 11, paragraph VII(A)3(a) of the brief, that Staskin fails to disclose a shaft with a straight portion, is incorrect. As the Appellant has pointed out, Staskin, in col. 23, lines 54-58, states that the "radius of curvature of the needle 60 may be substantially constant." The term "substantially" suggests that the needle is largely curved but not entirely curved. And

as seen the figures 12B and 16A, elements 58, 58A, 62A, or 170 are straight portions of the shaft connected to a curved portion (e.g., 60A). Additionally, the first spatulated section (126) indeed is connected to the curved portion (60A) by a flared section (the portion of 170 adjacent to 60A). That is, the first spatulated section is connected *via* the flared section to the curved portion. Claim 132 does not require a direct or in-line connection between the spatulated section and the curved portion, as suggested by the Appellant.

The allegation on page 12, paragraph VII(A)3(b) of the brief, that Staskin fails to disclose an elastically-biased latch portion in the handle, is incorrect. That is, figures 18C-18E of Staskin, as well as col. 25, lines 4-17, disclose that the latch portion (198) includes spring 208, which biases projections in a housing (202 and 204 combined) that engage the flat spatulated section. See fig. 18B reproduced below, which shows projections of the latch portion biased by spring 208.

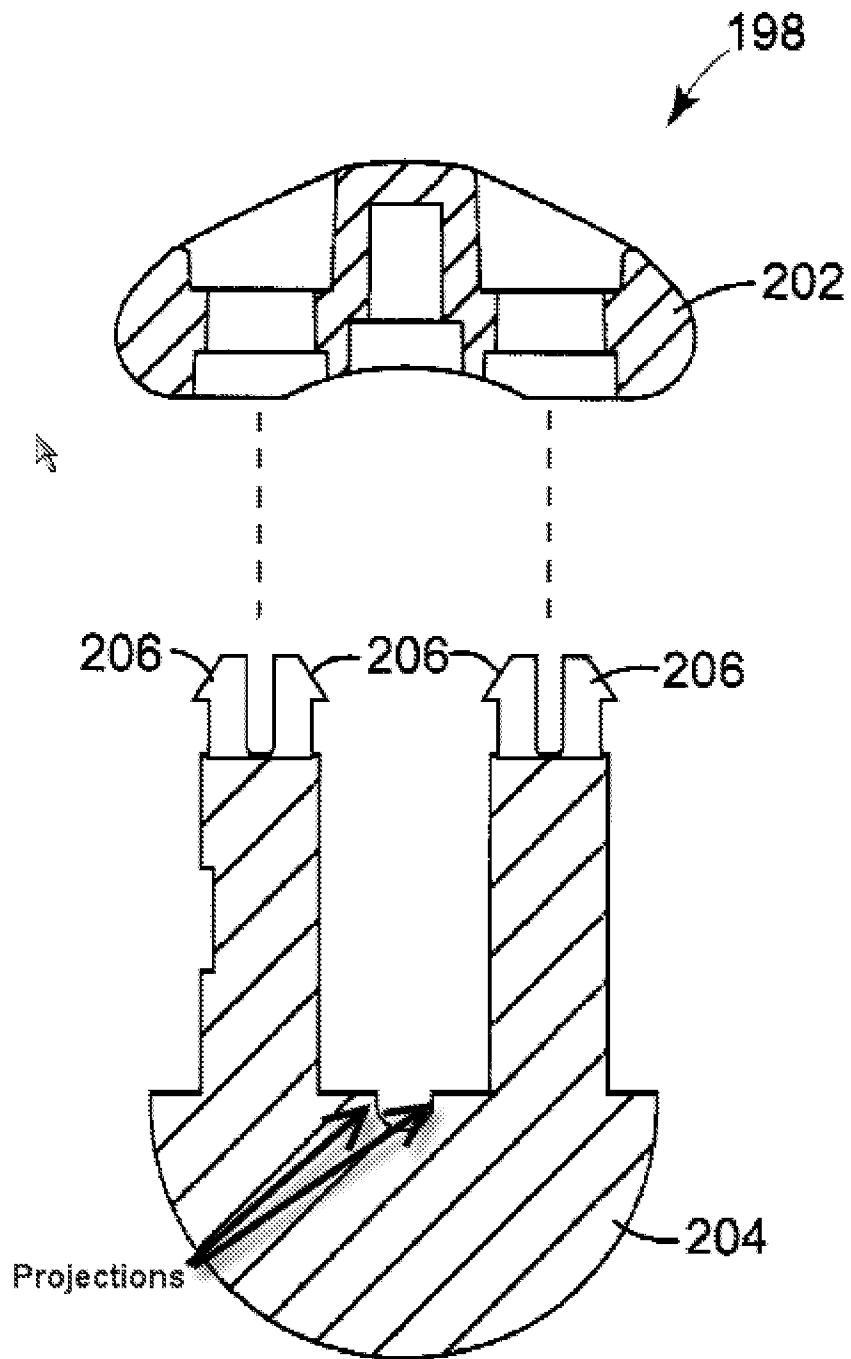


Fig. 18B

With respect to the allegation on page 14, paragraph VII(A)3(c) of the brief and regarding the teachings of Richmond: Richmond was not applied by the Examiner to show or describe a needle shaft with straight and curved portions, nor was Richmond applied for teachings regarding the latch portion. Again, Richmond was solely applied, in the rejection, for the teaching regarding an introducer needle possessing openings at its ends--a teaching applied for curing Staskin's deficiencies regarding such openings.

With respect to the allegation on page 14, paragraph VII(B) of the brief and regarding the teachings of Smith: Smith was not applied by the Examiner to substantially show or describe the system of claim 1. Smith was solely applied, in the rejection, for the teaching regarding an introducer needle with an oval cross-section as claimed.

With respect to the allegation on page 15, paragraph VII(C) of the brief and regarding the teachings of Gellman: Gellman was not applied by the Examiner to substantially show or describe the system of claim 1. Gellman was solely applied, in the rejection, for the teachings regarding an implant member as claimed.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Application/Control Number: 10/633,254
Art Unit: 3773

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Respectfully submitted,

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